



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,325	09/02/2003	Allan H. Graff	C75128-1	2971

7590 01/06/2006

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/653,325

Applicant(s)

GRAFF ET AL.

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/07/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of supplemental IDS, terminal disclaimer, and request for extension of time, amendment to the specification and claims, and remarks, all filed 10/07/05. Claims 1-32 are pending.

Drawings

Applicants' amendment to the specification to reflect proper heading and micro correction to the text for the section of the brief description of the drawings is acknowledged.

Claim Rejections - 35 USC § 112

1. The rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; and the rejection of Claims 16 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are both withdrawn in light of the amendment.

Claim Rejections - 35 USC § 102

2. Claims 1-4, 6-8 and 32 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ream et al. (US 6,290,985).

Applicants argue that Ream does not disclose each and every element of the claimed invention because Ream's formulation is a chewing gum comprising a tableted gum center that comprises a water-insoluble portion without the teaching of a glassy matrix suitable for oral dissolution; there is no disclosure that the ISOMALT present in Ream could be prepared as a glassy matrix suitable for oral dissolution because such would not be suitable as a chewing gum; and since Ream does not disclose a composition

Art Unit: 1618

comprising a glassy matrix “it cannot be said that Ream discloses that the amount of water-soluble gelling gum in the composition is present at a level that provides a desired dissolution rate of said glassy matrix.”

3. Applicants' arguments filed 10/07/05 have been fully considered but they are not persuasive.

It is noted that the glassy matrix comprises, according to claim 1, at least one substantially non-hygroscopic sugar alcohol that is capable of forming a glassy structure; the sugar alcohol is defined in claim 12 and the specification to be a mixture of 1,6-GPS (6-O- α -D-glucopyranosyl-D-sorbitol) and 1,1-GPM (1-O- α -D-glucopyranosyl-D-mannitol), which is ISOMALT. According to the claim is this sugar alcohol that is capable of forming a glassy structure. The prior art Ream discloses a composition that comprises ISOMALT and thus, in the same manner, this ISOMALT ought to have the ability to inherently form a glassy structure. The instant invention recites in the preamble that the dosage form is orally dissolving, the instant specification states on page 4, lines 30-35 that orally dissolvable may be “any form which is typically sucked, licked and/or chewed and eaten....” The instant claims are formulation/composition/dosage claims. The method of preparation is not claimed. The previous rejection follows below.

Ream discloses composition that comprises nicotine (column 8, line 58; column 9, line 6), guar gum hydrolysate (column 12, lines 62 and 63) and ISOMALT (column 7, line 49). Claims 32 and 33 recite future intended use of nicotine containing composition and future intended use is not critical in a composition claim.

Claim Rejections - 35 USC § 103

4. Claims 1-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ventouras (US 6,183,775 B1) in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Applicants argue that Ventouras in view of Rapp or Burnick does not teach each and every limitation of the claims, has no reasonable expectation of success, does not provide suggestion or motivation to modify the references or combine the teachings; and that Ventouras teaches away from the invention because

- a) Ventouras discloses formulations that contain swellable polymer as well as insoluble film forming agent in addition to soluble filler,
- b) the 1,1-GPS alone or in combination with other sweeteners are incorporated in Rapp to increase the flexibility of the gum and to prevent drying out of the gum during storage,
- c) the sweeteners of the type disclosed in Rapp are part of the brittle shell coating composition that encases a soft core in Burnick's oral dosage form. So that, applicants state, Rapp and Burnick and Ventouras do not disclose oral dosage form that comprises glassy matrix.

5. Applicants' arguments filed 10/07/05 have been fully considered but they are not persuasive.

- a) the comprising language of the claims is open and does not exclude the swellable polymer as well as insoluble film forming agent of Ventouras,

Art Unit: 1618

b) and c), the instant claims are composition claims that comprise glassy matrix that contain the sweeteners of Rapp and Burnick and because the sweeteners disclosed in Rapp and Burnick are the same sweeteners of the instant claims, it stands to reason that the function of the sweeteners would be the same even if the prior art is silent in one of the functions that may be identified by the instant claims; the instant claims are composition claims and the properties of a composition cannot be separated from the composition. MPEP 2112.01 [R-2] II states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. And "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Previous rejection follows.

Ventouras discloses controlled release lozenge that contains soluble filler namely maltitol, xylitol, sorbitol, mannitol, lactose, dextrose, saccharose, fructose and any mixture (column 1, lines 53 and 65-67; column 2, lines 1-8), insoluble film forming agent namely acrylates, EUDRAGIT, polyvinylpyrrolidone, cellulose acetate, shellac and cellulose acetate phthalate (column 2, lines 13-43), swellable polymer namely xanthan gum, guar gum, alginate and polysaccharides (column 2, lines 48-59), active agent such as nicotine tartrate, nicotine polacrilex and nicotine (column 3, lines 5-30) and auxiliaries that can be lubricants, flavors, aromas, sweeteners, buffering agents and glidants (column 3, lines 31-35). Specifically, nicotine formulation of Ventouras contains sodium carbonate or sodium bicarbonate (formulas 1-5). While Ventouras discloses nicotine formulations containing sweeteners such as aspartame,

Art Unit: 1618

saccharine, the formulation of Ventouras does not contain non-hygroscopic sugar alcohol as sweetener. However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1,6-GPS, 1,1-GPS and 1,1-GPM (abstract; column 4, lines 38-67). Also, Burnick discloses formulation that contains nicotine, ISOMALT and xanthan gum (abstract; paragraph [002]; paragraph [0012]; paragraph [0015]).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine lozenge as disclosed by Ventouras. One having ordinary skill in the art would have been motivated to include as an auxiliary a sweetener that is known in the art to be formulated with nicotine according to Rapp or Burnick with the expectation of imparting low hygroscopy to the lozenge and that sweetener is ISOMALT, a mixture of 1,6-GPS and 1,1-GPM.

6. Claims 10-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ream et al. (US 6,290,985).

Applicants argue that as previously stated, Ream, which discloses a chewing gum cannot be said to suggest that a non-hygroscopic sugar alcohol may be prepared as a glassy matrix suitable for oral dissolution because doing so would be conflicting the goal of Ream and that Ream does not contemplate a composition that comprises a “water-soluble gelling gum present at a level that provides the desired rate of glassy matrix;” that in Ream the guar gum hydrolysate may be “incorporated as a bulking agent where a low calorie gum is desired;” and that there is no suggestion in Ream that water soluble gelling gum is suitable for modifying the dissolution of non-hygroscopic sugar alcohol glassy matrix.

Art Unit: 1618

7. Applicants' arguments filed 10/07/05 have been fully considered but they are not persuasive.

As previous noted, glassy matrix comprises, according to claim 1, at least one substantially non-hygroscopic sugar alcohol that is capable of forming a glassy structure; the sugar alcohol is defined in claim 12 and the specification to be a mixture of 1,6-GPS (6-O- α -D-glucopyranosyl-D-sorbitol) and 1,1-GPM (1-O- α -D-glucopyranosyl-D-mannitol), which is ISOMALT. According to the claim is this sugar alcohol that is capable of forming a glassy structure. The prior art Ream discloses a composition that comprises ISOMALT and thus, in the same manner, this ISOMALT ought to have the ability to inherently form a glassy structure. The instant invention recites in the preamble that the dosage form is orally dissolving, the instant specification states on page 4, lines 30-35 that orally dissolvable may be "any form which is typically sucked, licked and/or chewed and eaten...." The instant claims are formulation/composition/dosage claims. The method of preparation is not claimed.

The instant claims which are directed to dosage/composition/formulation read on the composition of Ream. Regarding the amounts of gum present in the composition of the instant claims, e.g., claims 10 and 11, there is no demonstration with factual evidence that the recited amounts of the gum in claims 10 and 11 provide unusual and unexpected results to the instant composition. MPEP 2112.01 [R-2] II states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. And "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant

Art Unit: 1618

has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The instant compositions and the composition of the prior art contain ISOMALT, then the ISOMALT in both composition would reasonable be expected to have the same properties/function/intended use. A modification of the dissolution of the matrix containing ISOMALT is not required since the composition of the prior art contains ISOMALT.

The previous rejection is given below.

Ream discloses composition that comprises nicotine (column 8, line 58; column 9, line 6), guar gum hydrolysate (column 12, lines 62 and 63) and ISOMALT (column 7, line 49). Claims 32 and 33 recite future intended use of nicotine containing composition and future intended use is not critical in a composition claim. Ream does not disclose the amount of the gum. However, differences in amounts or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount or concentration is critical. And “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine composition of Ream and use the desired amounts of gum and active nicotine with the expectation of delivering nicotine to an individual.

Double Patenting

8. The provisional rejection of claims 1-33 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-33 of copending Application No. 10/244,782 is withdrawn because the application 10/244.782 is abandoned.

Art Unit: 1618

The provisional rejection of claim 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 52 of copending Application No. 10/471,477 is withdrawn in light of the cancellation of claim 33.

No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
Tech. Center 1600



MICHAEL HARTLEY
PRIMARY EXAMINER